



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 29088		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/IL2005/000228		International filing date (day/month/year) 24.02.2005	Priority date (day/month/year) 24.02.2004	
International Patent Classification (IPC) or national classification and IPC INV. C12M3/00 C12M1/04				
Applicant PROTALIX LTD. ET AL				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 22.09.2005		Date of completion of this report 21.04.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840		Authorized officer Clement, J-P Telephone No. +49 30 25901- 		

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IL2005/000228

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-73 as originally filed

Sequence listings part of the description, Pages

1-8 as originally filed

Claims, Numbers

1-159 as originally filed

Drawings, Sheets

1-27 as originally filed

- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-67,69-117,119-132,134-159
	No: Claims	1,68,118,133
Inventive step (IS)	Yes: Claims	
	No: Claims	1-159
Industrial applicability (IA)	Yes: Claims	1-159
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☒ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional observations, if necessary:

Re Item V.

- 1 Reference is made to the following document:

D1 : US 2002/110915 A1 (SHAALTIEL YOSEPH) 15 August 2002 (2002-08-15)

D2 : US 6 190 913 B1 (VIJAY SINGH) 20 February 2001 (2001-02-20)

2 INDEPENDENT CLAIMS 1 AND 68

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 68 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (claim 1, claim 50) :

a disposable device and a method for axenically culturing and harvesting cells/ or tissues,

said device comprising:

a sterilisable disposable container which may be at least partially filled with a sterile biological cell /or tissue culture medium comprising
(i) a gas outlet

(ii) an additive inlet

(iii) reusable harvesting means comprising suitable flow control means for enabling harvesting of at least a desired portion of said medium containing cells or tissues wherein a remainder of said medium containing cells and/or tissues, remaining from a previous harvested cycle, may serve as inoculant for a next culture and harvest cycle;

said method comprising:

providing a device such as described above

providing axenic inoculant via the harvesting means of the device

providing sterile culture medium and /or sterile additives via the additive inlet of the device

optionally illuminating the container contained with the device with external light allowing said cells and/or tissues to grow in said medium to a desired yield.

3 INDEPENDENT CLAIMS 118 AND 133

**INTERNATIONAL PRELIMINARY
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(SEPARATE SHEET)**

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- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 118 and 133 is not new in the sense of Article 33(2) PCT.

Document D1 discloses explicitly (par. 35) the use of a disposable device comprising a disposable container for culturing plant cells.

Document D2 discloses (col 3, lines 40-67) a device and a method for culturing plant cells the device comprising a disposable bag (4) and the method comprising culturing the plant cells in said disposable bag (4).

- 4 Dependent claims 2-67, 69-117, 119-132, 133-159 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, those claims relate to alternative design or method, not giving rise to any unexpected technical effect.